

REMARKS

The § 112 Objections

Claim 1 is amended to include the step of “(b) detecting cancerous cells *in vivo* which have been marked by the absorption of said agent in the mitochondria thereof.”

Claim 3 has been entirely rewritten to clarify and provide antecedent basis for “agent.”

The §102 Rejection

Bernal discloses that the survival time of mice injected “intraperitoneally” with Erlich ascites tumor cells and with leukemia , lung cancer and melanoma cells was improved in some but not all cases by intraperitoneal injection of rhodamine 123, concluding

“Our results may be the basis for clinical application of Rh123, as well as for a screening program to search for permeant cationic compounds more effective than Rh123.”

Aside from the fact that the increased survival time of the mice could just as well have been attributed to a decrease in growth rate of the tumors (as distinct from killing the tumor cells), the most that can be gleaned from **Bernal** is a classic “invitation to experiment,” suggesting that Applicant’s claimed invention was “obvious to try,” without a “reasonable expectation of success.” Amgen Inc. v. Chugai Pharmaceutical Co. , Ltd., 927 F.2d 1200, 1207-

1208 (Fed.Cir. 1991); In re O'Farrell , 853 F.2d 894, 903-04 (Fed.Cir. 1988).

To even further distinguish the claimed invention from the disclosure of *Bernal*, all of the claims are amended to recite that the agent is delivered “topically” rather than “intraperitoneally.”

Malmros discloses topical application of toluidine blue O containing an oxidizing agent but does not disclose the step of detecting which cells have been marked by the absorption of the agent into the cell mitochondria. Thus, *Malmros* did not disclose the key to the discovery of an entire class of agents, including compounds other than dyes, which would be useful in detecting cancerous tissue by selectively marking cellular mitochondria of the cancerous tissue.

To avoid and even more clearly distinguish the claimed invention over *Malmros*, all of the claims now restrict the agent to compounds “other than toluidine blue O.”

REQUEST FOR RECONSIDERATION

Reconsideration is respectfully requested in view of the foregoing amendments and remarks.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'W.H. Drummond', with a long horizontal flourish extending to the right.

William H. Drummond
Attorney for Applicant

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)

Applicant(s): Samuel D. Bernal, et al.

Docket No.

344-P-29-CIP-USA

Application No.

10/019,494

Filing Date

Feb. 27, 2001

Examiner

Customer No.

Group Art Unit


Invention: **METHOD FOR DETECTING AND KILLING EPITHELIAL CANCER CELLS**

I hereby certify that the following correspondence:

Amendments, Remarks, and Request for Reconsideration,

(Identify type of correspondence)

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

March 14, 2005*(Date)*Lynne J. Craig*(Typed or Printed Name of Person Mailing Correspondence)*
*(Signature of Person Mailing Correspondence)*EV 239479680 US*("Express Mail" Mailing Label Number)***Note: Each paper must have its own certificate of mailing.**